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*PATENT*
Attorney Docket No. **HOGAN-04448**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of : | Kirk Hogan | | |
| Serial No.: | 09/613,887 | Group No.: | 1655 |
| Filed: | 07/11/01 | Examiner: | J.E. Goldberg |
| Entitled: | Methods and Compositions for Perioperative Genomic Profiling | | |

# AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION DATED JUNE 5, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: 8/6/01 By: Susan M. McClintock
Susan M. McClintock

Madam:

The following communication is responsive to the Final Office Action mailed June 5, 2001, due on or before September 5, 2001. This communication is being filed with a Request for Continued Examination and should be considered as a preliminary amendment for examination purposes. The Applicant respectfully requests reconsideration of the Application in view of the following amendment and remarks.

A clean version of the rewritten, added, and/or cancelled claims with instructions for entry pursuant to 37 C.F.R., Section 1.121(c)(1)(i) is included beginning on the next page of this communication. A marked-up version of the rewritten, added, and/or cancelled claims pursuant to 37 C.F.R., Section 1.121(c)(1)(ii) is attached as Appendix I. A clean version of

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the entire set of pending claims pursuant to 37 C.F.R., Section 1.121(c)(3) as they should appear following entry of this amendment is attached as Appendix II.

**I. IN THE CLAIMS:**

Please cancel claims 1-20.

Please add the following claims:

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21. A method of screening a patient perioperatively to determine a risk for surgical complications associated with known genetic variations comprising:

a) obtaining a sample from a perioperative subject; and

b) subjecting said sample to an assay for detecting two or more genetic markers to generate a genomic profile for use in selecting a perioperative course of action, wherein said subjecting step occurs after said patient is scheduled for surgery but before completion of said surgery.

22. The method of Claim 21, wherein said course of action comprises administration of anesthesia during a surgical procedure.

23. The method of Claim 22, wherein said surgical procedure is non-invasive surgery.

24. The method of Claim 22, wherein said surgical procedure is invasive surgery.

25. The method of Claim 21, wherein said course of action comprises administration of anesthesia during a medical procedure.

26. The method of Claim 21, wherein said genomic profile comprises information pertaining to a pharmacodynamic risk.

27. The method of Claim 21, wherein said genomic profile comprises information pertaining to a pharmacokinetic risk.

28. The method of Claim 21, wherein said genomic profile comprises a presymptomatic diagnosis.

29. The method of Claim 21, wherein said genomic profile comprises information pertaining to differential diagnosis of co-existing diseases.

30. The method of Claim 21, wherein said two or more genetic markers comprise mutations in two or more genes, said genes selected from the group consisting of BChE, CYP2D6, MTHFR, MS, CBS, F 5 Leiden, Prothrombin, RYR1, CACNA1S, and CPT 2.

31. The method of Claim 21, further comprising the step of c) using said genomic profile for selection of conditions for a surgical procedure carried out on said patient.

32. A method for selecting conditions for a surgical procedure by screening a patient perioperatively to determine a risk for surgical complications associated with known genetic variations comprising:

a) providing a sample from a perioperative subject; and

b) subjecting said sample to an assay for detecting two or more genetic markers known to be associated with perioperative phenotypes to generate a genomic profile for use in selecting a surgical procedure treatment course of action; and

c) subjecting said subject to a surgical procedure, wherein conditions for said procedure are selected using said genomic profile.

33. The method of Claim 32, wherein said genetic markers are associated with a pharmacological response.

34. The method of Claim 33, wherein said pharmacological response is to an anesthetic.

35. The method of Claim 33, wherein said pharmacological response is to drugs used in anesthetic practice.

36. The method of Claim 32, wherein said two or more genetic markers comprises a mutation in two or more genes, said genes selected from the group consisting of BChE, CYP2D6, MTHFR, MS, CBS, F 5 Leiden, Prothrombin, RYR1, CACNA1S, and CPT 2.

37. A method of screening a patient perioperatively to determine a risk for surgical complications from known genetic variations comprising:

a) obtaining a sample from a perioperative subject; and

b) subjecting said sample to an assay for detecting two or more genetic markers clinically associated with two or more conditions selected from the group consisting of butyrylcholinesterase deficiency, poor debrisoquine metabolism, thrombus, and malignant hyperthermia to generate a genomic profile, wherein said genomic profile provides information for use by a physician in selecting a perioperative course of action.

38. The method of Claim 37, wherein said course of action comprises administration of anesthesia during a surgical procedure.

39. The method of Claim 38, wherein said surgical procedure is non-invasive surgery.

40. The method of Claim 38, wherein said surgical procedure is invasive surgery.

41. The method of Claim 37, further comprising the step of c) using said genomic profile for selection of conditions for a surgical procedure carried out on said patient.

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## REMARKS

Claims 1-20 were filed in the original case. Claims 1-20 are cancelled in the present amendment. These cancellations are made without acquiescing to the Examiner's rejections, but are made to further prosecution and Applicant's business interests. Applicant reserves the right to prosecute Claims 1-20 (or similar claims) in the future. Claims 21-41 are added with the present amendment. Therefore Claims 21-41 are currently pending.

In the Final Office Action dated June 5, 2001, the Examiner has withdrawn prior art rejections from the previous Office Action. However the Examiner maintained a number of rejections and added a new rejection. The currently pending rejections are:

1) Claims 1-20 stand rejected under 35 U.S.C. 112, first paragraph;

2) Claims 1 and 13 stand rejected under 35 U.S.C. 102; and

3) Claims 1-20 stand rejected under 35 U.S.C. 112, second paragraph.

Claims 1-20 are cancelled herein, rendering these rejections moot. During an in-person interview conducted on July 30, 2001, Applicant discussed these rejections with the Examiner in view of claim language similar to that provided in the currently pending claims. The Examiner indicated that the current prior art and Section 112 rejections would not be applicable to these claims. Applicant believes that the pending claims are enabled, definite, and are not taught or suggested by the prior art and therefore should be passed to allowance.

## CONCLUSION

All grounds of rejection of the Final Office Action of June 5, 2001 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicant's claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 8/6/01

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